

K251601 Hepatus 7/Hepatus 6/Hepatus 5/Hepatus 7S/Hepatus 6S/Hepatus 5S/Hepatus7T/Hepatus 6T/Hepatus 5T/Fibrous 7/Fibrous 6/Fibrous 5 Diagnostic UltrasoundSystemDec 3, 2025
190 days to decisionK251601 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k251601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 27, 2025
Decision date	Dec 3, 2025
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	Jing Tang
Website	https://www.mindray.com
510(k) history	156 submissions · 156 cleared · 2004-2026

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. is a medical technology and solutions supplier headquartered in Shenzhen, China. The company develops diagnostic imaging, patient monitoring, and clinical care devices. Mindray has received FDA 510(k) clearances from total submissions since 2004. The company specializes in diagnostic ultrasound systems and radiology devices, with a strong portfolio spanning general imaging, women's healthcare, cardiology, and liver care applications. Recent clearances include multiple ultrasound system variants and central monitoring plat...
